

II. REMARKS

Formal Matters

Claims 1-15 are pending after entry of the amendments set forth herein.

Claims 1, 2, and 6-11 were examined and were rejected. Claims 3-5, 12, and 13 were withdrawn from consideration.

Claim 1 is amended. The amendments to claim 1 was made solely in the interest of expediting prosecution, and is not to be construed as an acquiescence to any objection or rejection of any claim. Support for the amendments to claim 1 is found in the claims as originally filed, and throughout the specification, in particular at the following exemplary locations: paragraph 0029; and Examples. Accordingly, no new matter is added by these amendments.

Claims 14 and 15 are added. Support for new claims 14 and 15 is found in the claims as originally filed, and throughout the specification, including the following exemplary locations: paragraphs 00111 and 00117. Accordingly, no new matter is added by these new claims.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

Declaration

The Office Action stated that the Declaration is defective because the instant application claims priority of parent application 09/641,034 under 35 U.S.C. § 119(e) instead of 35 U.S.C. § 120 or 121.

Applicants submit herewith a Substitute Declaration, which addresses this issue.

Claim Objections

The Office Action objected to claims 3-5 as containing a non-elected invention.

Applicants note that the Office Action deemed claims 3-5 to be withdrawn from consideration, thereby rendering this objection to claims 3-5 moot.

Obviousness-type double patenting

Claims 1, 2, and 6-11 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claims 1-9 and 12-16 of co-pending U.S. Patent Application No. 09/641,034.

Upon issuance of a patent on U.S. Patent Application No. 09/641,034, Applicants will provide a terminal disclaimer, disclaiming the patent term beyond the expiration date of such patent.

Rejection under 35 U.S.C. § 102(b)

Claims 1, 2, 7, and 8 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Cheng et al. (U.S. Patent No. 5,849,865; “Cheng”).

The Office Action stated that Cheng teaches RGD-containing peptides such as SEQ ID NOs:79 and 80 which have 11 amino acids and bind to $\alpha 5\beta 1$ receptor, and can be used for treating osteoporosis and enhancing bone formation. Applicants respectfully traverse the rejection.

SEQ ID NO:79 and SEQ ID NO:80 of Cheng are circular (cyclic) peptides. Cheng, columns 85-86. The instant invention relates to peptide compounds that are linear. Accordingly, Cheng cannot anticipate the instant invention as claimed.

Furthermore, Cheng states that the peptides discussed therein inhibit bone resorption, and that they do so by inhibiting binding of osteoclasts to bone matrix. Cheng, Abstract; and column 1, lines 56-64. In contrast, the peptides as claimed in the instant application enhance bone growth.

Applicants submit that the rejection of claims 1, 2, 7, and 8 under 35 U.S.C. § 102(b) has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

Rejection under 35 U.S.C. § 102(a)

Claims 1, 2, 7, and 8 were rejected under 35 U.S.C. § 102(a) as allegedly anticipated by Rowe (WO 99/60017; “Rowe”).

The Office Action stated that Rowe teaches a phosphatonin peptide (SEQ ID NO:2, 430 amino acids, all L-configuration) that comprises 10-50 amino acids and an RGD domain, and further stated that the polypeptide can be used to improve impaired bone formation. Applicants respectfully traverse the rejection.

Claim 1 recites a peptide of from 10 to 50 amino acids in length. The claimed peptides comprise an integrin binding motif, as recited in claim 1. The claimed peptides enhance bone growth.

Rowe neither discloses nor suggests a peptide of from 10 to 50 amino acids in length that comprises an integrin binding motif or an RGD sequence, and that enhances or promotes bone growth. Accordingly, Rowe cannot anticipate claims 1, 2, 7, and 8.

Rowe relates to matrix extracellular phosphoglycoprotein (or “phosphatonin”). Rowe states that phosphatonin polypeptides can be used to treat disease, e.g., to improve impaired bone formation, and states that an MEPE motif is a pre-requisite for normal bone mineralization and growth. Rowe, page 49, lines 8-26. The MEPE motif is in the C-terminus of phosphatonin. Rowe, page 49, lines 22-26. There is no disclosure or suggestion in Rowe of any peptide of 10-50 amino acids in length and comprising an integrin binding motif, e.g., an RGD motif, which peptide is effective in enhancing bone growth. Accordingly, Rowe cannot anticipate the instant invention as claimed.

Applicants submit that the rejection of claims 1, 2, 7, and 8 under 35 U.S.C. §102(a) has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

Rejection under 35 U.S.C. §103

Claims 1, 2, and 7-11 were rejected under 35 U.S.C. §103 as allegedly unpatentable over Reynolds (U.S. Patent No. 5,015,628; “Reynolds”) taken with Rowe.

The Office Action stated: (1) Reynolds teaches phosphopeptides having 5-30 amino acids can be used for treating bone diseases, and the phosphopeptides can be formulated in a composition as toothpaste, mouthwash, and topical gel; (2) Reynolds does not disclose the composition comprising a peptide compound having an integrin binding motif; (3) Rowe teaches a phosphatonin polypeptide (SEQ ID NO:2, 430 amino acids, all L-configuration) that comprises 10-50 amino acids and an RGD domain, and further stated that the polypeptide can be used to improve impaired bone formation. The Office Action concluded that it would have been obvious to use the phosphatonin polypeptide having bone growth enhancing property as taught by Rowe for preparing the composition of toothpaste, mouthwash, or oral patch as taught by Reynolds. Applicants respectfully traverse the rejection.

As the Office Action acknowledged, Reynolds does not disclose a composition comprising a peptide compound having an integrin binding motif. As discussed above, Rowe neither discloses nor suggests a peptide of 10-50 amino acids in length and comprising an integrin binding motif, e.g., an RGD motif, which peptide is effective in enhancing bone growth. Accordingly, Reynolds, alone or in combination with Rowe, cannot render the instant peptide compound and formulation as claimed obvious.

Applicants submit that the rejection of claims 1, 2, and 7-11 under 35 U.S.C. §103 has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

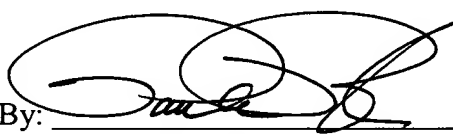
III. CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number BEAR006CIP.

Respectfully submitted,
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